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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,833	09/26/2003	Mark Edward Riehl	NNI-0005	1330

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EXAMINER	
HOPKINS, CHRISTINE D	
ART UNIT	**PAPER NUMBER**
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/672,833	RIEHL, MARK EDWARD	
	Examiner	Art Unit	
	CHRISTINE D. HOPKINS	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *28 Aug 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 28 August 2009. Claims 1-69 are now pending. The Examiner acknowledges the amendments to claims 1 and 67.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-21, 23, 24, 26-30, 35-51, 53-62, and 66-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Fox et al. (U.S. Pub. No. 2003/0050527). Fox et al. (hereinafter Fox) disclose an apparatus and method for delivering transcranial magnetic stimulation. Regarding claims 1-6, 20, 21, 23, 24, 36, 37 and 40-43, Fox teaches a circuit pad comprising a flat metallic conductor (copper windings) encased in plastic and located proximate to a magnetic stimulator (Figs. 12 and 13) inducing a strong magnetic field at around 2 Tesla [0006]. Standard connections from the coil to cabling necessary to adapt the coil to a magnetic stimulator are present. A minimum inductance configuration may also be achieved for peripheral nerve stimulation ([0153]-[0154]). A predetermined location, such as a peripheral nerve portion, may be located

prior to stimulation ([0028]-[0029]). Regarding claims 7-17, the "disposal mechanism" is interpreted as the thermally conductive epoxy used to enhance heat dissipation [0153] because its removal would render the circuit pad inoperable since its purpose is to reduce stimulation on the brain induced by the stimulation device. The epoxy permits the patient to use the circuit pad for a certain period of time since it reduces heat received to the scalp of the patient while stimulation is conducted.

Regarding claims 18-19, the circuit pad would become inoperable and would also be capable of disintegrating if placed in contact with certain cleaning solutions.

With respect to claim 26, the stimulation may be reduced by reducing magnetic flux density caused by the stimulation device [0160]. With respect to claim 27, the conductors and the magnetic stimulation device are both fully capable of creating magnetic fields. Regarding claims 28-30, the conductors and stimulation device are both fully capable of being provided with electrical energy of opposite polarities substantially simultaneously [0079].

In view of claims 35, 38 and 39, a relatively longer dimension of the conductor, which also has a portion which is "arc-shaped," is placed along a similar direction as a electric field vector induced by a magnetic stimulation device (Fig. 1).

Regarding claims 44-47, 49, 51, 61-62 and 66, Fox teaches a method for using transcutaneous magnetic stimulation whereby a strong magnetic field (2 Tesla) created by a magnetic stimulation device is directed to a treatment area (scalp as in Fig. 4) on a patient, wherein a flexible circuit pad comprising at least one conductor adapted to reduce stimulation induced by the stimulation device, is connected to the TMS system

and placed in the treatment area of the patient ([0006], and [0153]-[0154]). Regarding claim 48, while the specification does not provide adequate disclosure for a magnetic stimulation device having a magnetic core with a "non-toroidal geometry," it is understood by the plain definition of the term of "toroidal" to be "donut-shaped," and thus the core of the magnetic stimulation device of Fig. 7 is "non-toroidal" and anticipates the claim.

Regarding claim 50, a predetermined location, such as a peripheral nerve portion, may be located prior to stimulation ([0028]-[0029]).

Regarding claims 53-60, the "disposal mechanism" is interpreted as the thermally conductive epoxy (also considered to be insulative) used to enhance heat dissipation [0153] because its removal would render the circuit pad inoperable since its purpose is to reduce stimulation on the brain induced by the stimulation device. The epoxy permits the patient to use the circuit pad for a certain period of time since it reduces heat received to the scalp of the patient while stimulation is conducted.

Regarding claims 67-69, the body portion of the stimulator may be made of air, ferrite or other materials [0079].

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 22 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (U.S. Pub. No. 2003/0050527) in view of Mechlenburg et al. (U.S. Pub. No. 2001/0018547). Fox discloses the invention as claimed, see rejection supra; however Fox does not disclose expressly that the circuit pad comprises an adhesive. Mechlenburg et al. (hereinafter Mechlenburg) teaches a device and method for magnetic stimulation to treat various disorders. Regarding claims 22 and 63, Mechlenburg teaches a magnetic stimulation device **30** comprising a collar portion for wrapping around the neck of the patient and a coil for generating the magnetic field [0032]. The collar is attached to the patient using any suitable method, such as an adhesive [0072]. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to have to have utilized an adhesive as taught by Mechlenburg, in order to secure a pad comprising a stimulation coil to a patient as taught by Fox, for ensuring that the proper treatment area is stimulated.

6. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (U.S. Pub. No. 2003/0050527). Fox discloses the invention as claimed, see rejection supra; however Fox does not disclose expressly that the conductor of the circuit pad has an area in the range of 1 cm^2 to 40 cm^2. Instead, Fox indicates that the conductors may have a diameter between about 0.1 mm and 1.0 mm which will be placed on the scalp of a patient ([0150]-[0153]). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to construct a circuit pad having conductors with a an area in such dimensions provide an advantage, is used for a particular purpose, or solves a stated problem as opposed to

any other which would be used on the scalp of a patient. One of ordinary skill in the art would have expected Fox's circuit pad and applicant's invention, to perform equally well with either the dimensions taught by Fox or the claimed flexible dimensions because both would perform the same function of enabling stimulation to the scalp of a patient. Therefore, at the time of the invention it would have been prima facie obvious to modify Fox to obtain the invention as specified in claim 25 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Fox.

7. Claims 31-34, 52 and 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (U.S. Pub. No. 2003/0050527) in view of Henley et al. (U.S. Patent No. 6,477,410). Fox discloses the invention as claimed, see rejection supra; however Fox fails to disclose a conductive gel facilitating communication between the circuit pad and a treatment area. Henley et al. (hereinafter Henley) disclose a device for self-administration of medicament to a treatment site. Regarding claims 31-33, Henley teaches a conductive gel that facilitates electrical conduction between a treatment area and an electrode **30** of an applicator. The conductive gel may be provided within a porous, or "absorbent" substrate **42** of pad **44**. The porous substrate **42** is interpreted as a sponge material (col. 20, lines 48-61). In view of claim 34, the substrate may also be made of a plastic material, and shaped according to an individual's anatomy. Fox, likewise, incorporates an assembly that considers the anatomy of a patient's skull for treatment. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have introduced a conductive gel for delivering

treatment to an individual as suggested by Henley, to a device for reducing pain for an ailment to the head as suggested by Fox, for providing increased contact between the device and the individual for effective treatment of the site of interest.

Regarding claims 52 and 64-65, Henley teaches that a conductive gel may be applied between the circuit pad and the patient (col. 20, lines 48-61). The substrate of the circuit pad may also be made of a plastic material, and shaped according to an individual's anatomy (col. 21, lines 31-39). Similarly, Fox teaches constructing the treatment assembly of materials that enable treatment of the brain. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have introduced a conductive gel for enabling better contact between a patient and a conductor as suggested by Henley, to a device enabling specific treatment to a patient as taught by Fox, to more effectively provide treatment at a particular area of interest on a patient.

Response to Arguments

8. Applicant's arguments filed 28 August 2009 with respect to the rejection of claims 1-21, 23, 24, 26-30, 35-51, 53-63, and 66-69 under 35 U.S.C. 102(e) citing Fox et al. (U.S. Pub. No. 2003/0050527) have been fully considered and are not persuasive. Applicant contends that the conductor taught by Fox is not located "proximate to" a magnetic stimulation device as recited by claim 1. However, this argument is not persuasive. At paragraph [0153], as noted in the rejection above, standard connections from the coil to cabling may be made in order to adapt the coil to a magnetic stimulator.

Since a connection exists between the conductor and the magnetic stimulation device, it is noted that the conductor is considered to be "proximate" to a magnetic stimulation device. In view of the foregoing, the rejection of claims 1-21, 23, 24, 26-30, 35-51, 53-63, and 66-69 under 35 U.S.C. 102(e) citing Fox et al. (U.S. Pub. No. 2003/0050527) has been maintained.

9. Applicant's arguments filed 28 August 2009 with respect to the rejection of claims 22 and 63 under 35 U.S.C. 103(a) citing Fox et al. (U.S. Pub. No. 2003/0050527) in view of Mechlenburg et al. (U.S. Pub. No. 2001/0018547) have been fully considered and are not persuasive. Applicant's arguments are contingent upon those presented with regards to claim 1, which are addressed above. In view of the foregoing, the rejection of claims 22 and 63 under 35 U.S.C. 103(a) citing Fox et al. (U.S. Pub. No. 2003/0050527) in view of Mechlenburg et al. (U.S. Pub. No. 2001/0018547) has been maintained.

10. Applicant's arguments filed 28 August 2009 with respect to the rejection of claim 25 under 35 U.S.C. 103(a) citing Fox et al. (U.S. Pub. No. 2003/0050527) have been fully considered and are not persuasive. Applicant's arguments are contingent upon those presented with regards to claim 1, which are addressed above. In view of the foregoing, the rejection of claim 25 under 35 U.S.C. 103(a) citing Fox et al. (U.S. Pub. No. 2003/0050527) has been maintained.

11. Applicant's arguments filed 28 August 2009 with respect to the rejection of claims 31-34, 52 and 64-65 under 35 U.S.C. 103(a) citing Fox et al. (U.S. Pub. No. 2003/0050527) in view of Henley et al. (U.S. Patent No. 6,477,410) have been fully considered and are not persuasive. Applicant's arguments are contingent upon those presented with regards to claim 1, which are addressed above. In view of the foregoing, the rejection of claims 31-34, 52 and 64-65 under 35 U.S.C. 103(a) citing Fox et al. (U.S. Pub. No. 2003/0050527) in view of Henley et al. (U.S. Patent No. 6,477,410) has been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is

(571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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